



**U.S. FOOD & DRUG
ADMINISTRATION**



GETTING STARTED: CREATING AN ESG ACCOUNT

eCTD

The FDA Electronic Submissions Gateway (ESG) is the central transmission point for sending information electronically to FDA.

There are three methods for submitting to the ESG

AS2 Gateway-to-Gateway Connection

- Generally used by sponsors that have a high volume of submissions
- Allows automated submissions
- Requires AS2-compliant software and technical expertise

WebTrader

- A regular desktop computer can be used for submissions
- User can only send one submission at a time
- Requires installation of a Java applet but minimal technical expertise

WebTrader Hosted Solution

- Allows the user to submit via WebTrader without installing the Java applet

Registration process

Registering to use the FDA ESG involves a sequence of steps that are to be conducted for all submitters and types of submissions. It is best to start well in advance of the time when you plan to make a submission.

The process includes a testing phase designed to ensure that the FDA ESG can successfully receive your electronic submission and that the electronic submission is prepared according to published guidelines. The testing phase is done through the FDA ESG test system. Once the submitter's test submission has passed the testing phase, an account will be set up allowing submissions to be sent through the FDA ESG production system.

Where to get started

All relevant information, including detailed descriptions of the steps and contact information for requests and assistance, can be found on the FDA ESG website: www.fda.gov/esg

Contact information

If you have questions for CDER, please contact **CDER ESUB** at esub@fda.hhs.gov

If you have questions for CBER, please contact **CBER ESUB** at esubprep@fda.hhs.gov

Overview of process

1. Request an account

You will start with a test account.

2. Preparatory activities

Steps include arranging for FDA to accept electronic signatures.

3. Register your test account

4. Set up your machine for ESG

This includes configuring your firewall according to instructions provided by FDA.

5. Send test submissions

All users must submit a test submission. AS2 users must also carry out a load test.

6. Production account approval